K041080

section 10: 510(K) SUMMARY NOV 3 0 2004

510(K) Summary of Safety and effectiveness

Trade name: Surgical Drape Kit - D.I.R.R.A. srl

Common name: Surgical Drape Kit

Classification name: 878.4370 Surgical Drape and Drape Accessories

Official contact:

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Predicate devices - 510(K) Nr: k934688:
The Surgical Drape Kit - produced by D.I.R.R.A. srl, is substantially equivalent to: Custom Surgical Pack - distributed by Nobelbiocare and Produced by Maxxim under the previous name of Sterile Design Inc.

Intended use:
kit for oral implantology, used by dental professionals when performing surgical procedures

Indications for Use:

The D.I.R.R.A. surgical drape device kit is composed of natural or synthetic materials and intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial or other contamination.

Comparison to predicate devices (501(k) number k934688):
These devices have the same indications for use (kit for oral implantology), and almost the same components, with the same technological characteristics (materials, sterility, dimensions).
differences between D.I.R.R.A. srl - Surgical Drape Kit and the predicate device should not affect the safety and effectiveness (The determination of substantial equivalence is not based on an assessment of performance data.).

Device Description

The DIRRA surgical drape device kit is composed of natural or synthetic materials and intended to be used as protective patient covering, such as to isolate a site of surgical incision from microbial or other contamination. The DIRRA surgical drape device kit is to be used by medical and dental professionals when performing surgical procedures.

The DIRRA surgical drape device kit consists of the following components:

Component	**Pieces**	**Regulatory Clearance Status**	**Manufacturer**
Gown w/ paper towel	2	K012186	Master & Frank Surgical
Mayo stand cover	1	n/a	/
Sterile sheet	1	K020393	Master & Frank Surgical
Patient drape	1	K020393	Master & Frank Surgical
Transparent drape	1	n/a	/
Adhesive strip	4	n/a	/
Tube holder	1	n/a	/
Cord drape	2	n/a	/
Suction tubing w/tip	1	n/a	/
Flat gauze	20	n/a	/
Round gauze sponge	5	n/a	/
Plastic tray	1	n/a	/
Transparent adhesive film	3	n/a	/
Connector for suction tubing	1	n/a	/
Kit wrapping drape	1	n/a	/
			/

All the components are wrapped in the DIRRA surgical drape device kit wrapping drape which is closed with a label.

The final measurement of the kit (not enveloped) is approximately cm.30x30x10. The kit is then enveloped in sequence and in accordance with the instructions for use. The pack is then inserted in the Sterilization plastic/tyvek pouch and the pouch is sealed. 2 Kits are put into one cardboard box along with instructions for use,. The box is then closed and sterilized by Bioster. A sterilization batch number is applied on the box after the sterilization process has been completed.

Following is a further description of the DIRRA surgical kit components:

Gown w/ paper towel
The gown Nr.1 is a Surgical gown in Non Woven PGI water repellent, blue color. This fabric has a high tensile strength and toughness that is also soft, drapeable and easy to work with. In addition, a high fluid and particulate barrier is complimented by excellent breathability while preventing strike-through of fluid and bacteria to meet the need of a wide variety of applications. A paper towel is packaged with the gown and is composed of 100% cellulose;
The gown size is L and this is the only one size provided in the kit. The gown measures are reported in the technical sheet Nr. 1, located on page __of this response.
There are no reinforced areas in the gown. The internal code is 12.D1111.00.
The material used for the gown is Non Woven PGI6920 is a spunlaced fabric of 5% Woodpulp and 45% polyester staple fibres. The fabric consists of tightly interlaced fibres which do not allow bacteria to penetrate but do let air circulate freely, are soft, drapable and show good dry and wet strength. There are 2 gowns in 1 kit.
The gown is made for a single-use only. It also prevents cross-contamination in the operating theatre by its single-use (disposable).

Mayo stand cover
The Mayo stand cover Nr.2 compound by two layers, one absorbent and one waterproof, for protection of the Mayo table in the operating theatre. The type of material is Absorbent layer (High absorbent Non Woven color blue) and Waterproof layer (Polyethylene tubular color blue). The mayo cover size is cm. 80 x 140. It is intended to be used to cover the medical table and to maintain the sterile field as well as an aid in the clean up of equipment after surgery. There is 1 Mayo stand cover in the Kit. This cover is not intended to be used as patient drape and has no patient contact. The internal code is 12.A1003.00.

Sterile sheet
The sterile sheet Nr.3 is made of Non Woven PGI6920 water repellent. This fabric has a high tensile strength and toughness that is also soft, drapeable and easy to work with. In addition, a high fluid and particulate barrier is complimented by excellent breathability while preventing strike-through of fluid and bacteria to meet the need of a wide variety of applications The color is blue and the measurement is 100x100cm (square shape). It is intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. There is 1 sterile sheet in the Kit. The internal code is 10.A1701.00.

Patient drape
The patient drape (split drape) Nr.4 is made of Non Woven PGI6920 water repellent fabric. This fabric has a high tensile strength and toughness that is also soft, drapeable and easy to work with. In addition, a high fluid and particulate barrier is complimented by excellent breathability while preventing strike-through of fluid and bacteria to meet the need of a wide variety of applications. It is intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. There is 1 patient drape, containing a hole, in the Kit. The internal code is 10.T1762.00.

Transparent drape
The transparent drape Nr.5 is composed of Polyethylene and is used to reduce cross contamination risk. It measures 50x40 cm. It is intended to be used to cover the medical table or equipment in order to maintain the sterile field and as an aid in the clean up of equipment after surgery. This cover is not intended to be used as a patient drape and has no patient contact. The internal code is 12.A1003.00. There is 1 transparent drape in the Kit.
The drape has an adhesive strip applied on the short side (cm.40x4).

Adhesive strip
The Adhesive strip Nr.6 is composed of a non woven fabric and medical adhesive for fixation on human skin. It is a device intended to be placed on the skin to attach a surgical drape.
The measures are: cm. 15x2,5, the color is white. There are 4 strips in the Kit; the internal code is 30.A0063.00

Tube holder
The Tube holder Nr.7 is a non woven fabric water repellent SMS, blue color. The measurements are cm 11cm.(width)x12cm.(base) and the shape is that of a semicircle with three holes. It is used as a drape accessory to hold tubes that may be necessary during the operating procedure. It is affixed to the drape via an adhesive strip for fixation (14,5x2 cm.) applied on the base which protrudes 2,5cm. There is 1 tube holder in the Kit. The internal code is 10.A0037.00.

Cord drape
The Cord drape Nr.8 is a plastic transparent cover for protection of the power cord, motor and the contra angle. It is intended to be used to cover the medical table or equipment in order to maintain the sterile field and as an aid in the clean up of equipment after surgery.
It is composed of Polyethylene in a tubular fashion with a diameter of 7cm.and length of 140 cm. and wrapped around a carton used to assist in keeping the cord from becoming entangled. It also has 2 elastic bands (latex free). There are 2 cord drapes in the Kit. The internal code is: 20.U0007.00.

Suction tubing w/tip

The Suction tube, with cannula Nr.9, is used for surgical suctioning of blood and secretion. It is not an invasive device and it is used only inside the mouth. It is composed of a suction tube, a cannula for suction, and connector for suction tubing. It is intended to be used in an oral cavity evacuator. The suction tube is transparent and composed of PVC. Its measurements are:
Length: 2450 mm ± 70,00 mm.
Inner Diameter : 6,25 mm. ± 0,1 mm.
Outer Diameter : 8,80 mm ± 0,1 mm.
The cannula is transparent, made of PVC and the measures are:
Length: 155 mm ± 0,5 mm.
Inner Diameter : 2,6 mm. ± 0,1 mm.
Outer Diameter : 4,6 mm ± 0,1 mm.
There is 1 suction tube in the Kit. The internal code is: 30.F5151.00

Flat gauze

The Flat gauze Nr.10 is a gauze composed of 100% cotton for use in wound cleaning, prepping, scrubbing, packing, or dressing situations. Its measurements are cm. 7,5 x 7,5.
Edges are folded, not cut to reduce threads and lint loss. There are 20 Flat gauzes in the kit.
The internal code is 20.A0100.00.

Round gauze sponge

The round Gauze Sponge Nr.11 is composed of 100% cotton that offers uses for wound cleaning, scrubbing, or dressing situations. It measures ø 5 cm. and the color is white. There are 5 round gauzes in the Kit. The internal code is 30.V0013.00.

Plastic tray

The plastic tray Nr.12 is composed of Polyethylene, in a "U" shape and the measurements are: Length 250 mm. Width 135 mm. Depth 350 mm. It is intended to be held by a dental handpiece and used to apply the polishing agent during prophylaxis. There is 1 plastic tray in the Kit. The internal code is 30.V0013.00.

Transparent adhesive film

The transparent adhesive film Nr.13 is a Polyethylene Adhesive Plastic film and is used to reduce the cross contamination risk. The measurements are: 200x200 mm. The adhesive (applied all along 1 of the surfaces) is acrylic in solution. It is intended to be used to cover the medical table or equipment in order to maintain the sterile field and as an aid in the clean up of equipment after surgery. This cover is not intended to be used as a patient drape and has no patient contact. There are 3 Transparent adhesive films in the Kit. The internal code is 30.V0020.00.

Connector for suction tubing

The connector for the suction tube Nr. 14 is made of PVC and the measurements are:

Length: 5,8cm.

Max Diameter: 10mm

It is composed of 5 different sectors with different diameters (1 sector of 10mm, 2 sectors of 7mm and 2 sectors of 6,4 mm).There is 1 connector for suction tubing in the Kit. The internal code is: 30.Z1070.00

Kit wrapping drape

The kit wrapping drape Nr.15 is an instrument Table drape made of non woven absorbent material and a polyethylene plastic film. The drape measures cm. 160 x 190 cm., the color of both material is blue and it is intended to be used to cover the medical table or equipment in order to maintain the sterile field and as an aid in the clean up of equipment after surgery. Their cover is not intended to be used as a patient drape and has no patient contact. There is 1 Kit wrapping drape in the Kit. The internal code is 30.A1006.00.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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NOV 3 0 2004

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Re: K041080
Trade/Device Name: Surgical Drape Kit
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: LRO
Dated: November 5, 2004
Received: November 5, 2004

Dear Mrs. Bacchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k041080

Device Name: Surgical Drape Kit

Indications for Use: The D.I.R.R.A. surgical drape device kit is composed of natural or synthetic materials and intended to be used as a protective patient covering, such as isolate a site of surgical incision from microbial or other contamination.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: k041080